

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

THE RESEARCH FOUNDATION OF
STATE UNIVERSITY OF NEW YORK;
NEW YORK UNIVERSITY; GALDERMA
LABORATORIES INC.; AND GALDERMA
LABORATORIES, L.P.,

Plaintiffs,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 09-483 (HB)

**LUPIN PHARMACEUTICALS, INC. AND LUPIN LTD.'S
ANSWER, DEFENSES AND COUNTERCLAIM**

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin") hereby answer the Complaint of Plaintiffs, The Research Foundation of State University of New York, New York University, Galderma Laboratories Inc., and Galderma Laboratories, L.P., as follows:

PARTIES

1. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

2. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

3. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

4. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

5. Lupin admits that Lupin Ltd. is an Indian corporation having its only places of business in India, including at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Lupin denies all remaining allegations of Paragraph 5.

6. Lupin admits that LPI is a Virginia corporation with a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Ltd. Lupin denies that LPI is a proper party to this action, and denies all remaining allegations of Paragraph 6.

NATURE OF THE ACTION

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this action purports to allege infringement of U.S. Patent Nos. 7,232,572 (“the ‘572 patent”); 7,211,267 (“the ‘267 patent”); 5,789,395 (“the ‘395 patent”); and 5,919,775 (“the ‘775 patent”). Lupin further admits that what purports to be copies of the ‘572 patent, the ‘267 patent, the ‘395 patent and the ‘775 patent are attached to the Complaint as Exhibits A-D, respectively. Lupin denies the remaining allegations of Paragraph 7.

JURISDICTION AND VENUE

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits subject matter jurisdiction for the claims asserted against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A) only. Lupin denies subject matter jurisdiction for any claim against LPI. Lupin denies the remaining allegations of Paragraph 8.

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest personal jurisdiction in this judicial district for purposes of this action only. Lupin denies that LPI is a proper party to this action. Lupin denies the remaining allegations of Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest personal jurisdiction in this judicial district for purposes of this action only. Lupin denies that LPI is a proper party to this action. Lupin denies the remaining allegations of Paragraph 10.

11. Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest venue for the purpose of this action only. Lupin denies that LPI is a proper party to this action. Lupin denies all remaining allegations of Paragraph 11.

THE PATENTS-IN-SUIT

12. Lupin admits that the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "Galderma Labs LP" as the "applicant" for approved New Drug Application ("NDA") No. 50-805 for Oracea[®] (doxycycline) Capsules, 40 mg. Lupin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 12, and therefore denies these allegations.

13. Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '572 patent, entitled "Methods of Treating Rosacea," on or about June 19, 2007; that the cover page of the '572 patent identifies "CollaGenex Pharmaceuticals, Inc." as the purported "assignee"; and that what purports to be a copy of the '572 patent is attached to the Complaint as Exhibit A.

Lupin denies that the '572 patent was "duly and legally issued." Lupin denies all remaining allegations of Paragraph 13.

14. Lupin admits that the electronic version of FDA's Orange Book lists the '572 patent in connection with Oracea[®]. Lupin denies all remaining allegations of Paragraph 14.

15. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

16. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, the PTO issued the '267 patent, entitled "Methods of Treating Acne," on or about May 1, 2007; that the cover page of the '267 patent identifies "CollaGenex Pharmaceuticals, Inc." as the purported "assignee"; and that what purports to be a copy of the '267 patent is attached to the Complaint as Exhibit B. Lupin denies that the '267 patent was "duly and legally issued." Lupin denies all remaining allegations of Paragraph 17.

18. Lupin admits that the electronic version of FDA's Orange Book lists the '272 patent in connection with Oracea[®]. Lupin denies all remaining allegations of Paragraph 18.

19. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

20. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

21. Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic

records of the PTO, the PTO issued the '395 patent, entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production," on or about August 4, 1998; that the cover page of the '395 patent identifies "The Research Foundation of State University of New York" and "Hospital for Joint Diseases" as the purported "assignees"; and that what purports to be a copy of the '395 patent is attached to the Complaint as Exhibit C. Lupin denies that the '395 patent was "duly and legally issued." Lupin denies all remaining allegations of Paragraph 21.

22. Lupin admits that the electronic version of FDA's Orange Book lists the '395 patent in connection with Oracea[®]. Lupin denies all remaining allegations of Paragraph 22.

23. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

24. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

25. Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, the PTO issued the '775 patent, entitled "Method for Inhibiting Expression of Inducible Nitric Oxide Synthase with Tetracycline," on or about July 6, 1999; that the cover page of the '775 patent identifies "The Research Foundation of State University of New York" and "Hospital for Joint Diseases" as the purported "assignees"; and that what purports to be a copy of the '775 patent is attached to the Complaint as Exhibit C. Lupin denies that the '775 patent was "issued" on April 16, 1998 or was "duly and legally issued." Lupin denies all remaining allegations of Paragraph 25.

26. Lupin admits that the electronic version of FDA's Orange Book lists the '775 patent in connection with Oracea[®]. Lupin denies all remaining allegations of Paragraph 26.

27. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

28. Lupin is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

ACTS GIVING RISE TO THIS ACTION

Count I -- Infringement of the '572 Patent

29. Lupin restates, reasserts and incorporates by reference each of its responses to paragraphs 1 through 28 as if fully set forth herein.

30. Lupin admits that Lupin Ltd. has submitted an Abbreviated New Drug Application ("ANDA") to FDA for Doxycycline Delayed Release Capsules, 40 mg. Lupin denies all remaining allegations of Paragraph 30, and denies that LPI is a proper party to this action.

31. Lupin admits that Lupin Ltd.'s ANDA seeks FDA approval for Doxycycline Delayed Release Capsules, 40 mg. Lupin denies all remaining allegations of Paragraph 31.

32. Lupin admits that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '572 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of the Doxycycline Delayed Release Capsules, 40 mg, that are the subject of Lupin Ltd.'s ANDA. Lupin denies all remaining allegations of Paragraph 32.

33. Lupin admits that Lupin Ltd.'s ANDA seeks FDA approval for Doxycycline Delayed Release Capsules, 40 mg before the expiration of the '572 patent. Lupin denies all remaining allegations of Paragraph 33.

34. Lupin admits that, by letter dated May 29, 2009, Lupin Ltd. provided the requisite and timely notice to Galderma Laboratories, L.P., Galderma Laboratories Inc., New York University, and The Research Foundation of State University of New York of Lupin Ltd.'s ANDA seeking FDA approval for Doxycycline Delayed Release Capsules, 40 mg, before the expiration of the '395, '775, '267 and '572 patents. Upon information and belief, Galderma Laboratories, L.P., Galderma Laboratories Inc., New York University, and The Research Foundation of State University of New York timely received this notice. Lupin denies all remaining allegations of Paragraph 34.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

Count II - Infringement of the '267 Patent

40. Lupin restates, reasserts and incorporates by reference each of its responses to paragraphs 1 through 39 as if fully set forth herein.

41. Lupin admits that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '267 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of the Doxycycline Delayed Release Capsules, 40 mg, that are the subject of Lupin Ltd.'s ANDA. Lupin denies all remaining allegations of Paragraph 41.

42. Lupin admits that Lupin Ltd.'s ANDA seeks FDA approval for Doxycycline Delayed Release Capsules, 40 mg before the expiration of the '267 patent. Lupin denies all remaining allegations of Paragraph 42.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

Count III - Infringement of the '395 Patent

48. Lupin restates, reasserts and incorporates by reference each of its responses to paragraphs 1 through 47 as if fully set forth herein.

49. Lupin admits that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '395 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of the Doxycycline Delayed Release Capsules, 40 mg, that are the subject of Lupin Ltd.'s ANDA. Lupin denies all remaining allegations of Paragraph 49.

50. Lupin admits that Lupin Ltd.'s ANDA seeks FDA approval for Doxycycline Delayed Release Capsules, 40 mg before the expiration of the '395 patent. Lupin denies all remaining allegations of Paragraph 50.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

Count IV - Infringement of the '775 Patent

56. Lupin restates, reasserts and incorporates by reference each of its responses to paragraphs 1 through 55 as if fully set forth herein.

57. Lupin admits that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '775 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of the Doxycycline Delayed Release Capsules, 40 mg, that are the subject of Lupin Ltd.'s ANDA. Lupin denies all remaining allegations of Paragraph 57.

58. Lupin admits that Lupin Ltd.'s ANDA seeks FDA approval for Doxycycline Delayed Release Capsules, 40 mg before the expiration of the '775 patent. Lupin denies all remaining allegations of Paragraph 58.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation of the Complaint not otherwise admitted, and without assuming any of the burdens imposed by law on the Plaintiff, Lupin asserts the following separate defenses:

First Defense

The manufacture, use, sale, offer for sale, or importation of the drug product described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not – if marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of U.S. Patent No. 5,789,395 (“the ‘395 patent”), either literally or under the doctrine of equivalents.

Second Defense

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ‘395 patent.

Third Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ‘395 patent.

Fourth Defense

The claims of the ‘395 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Fifth Defense

The manufacture, use, sale, offer for sale, or importation of the drug product described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not – if marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of U.S. Patent No. 5,919,775 (“the ‘775 patent”), either literally or under the doctrine of equivalents.

Sixth Defense

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '775 patent.

Seventh Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '775 patent.

Eighth Defense

The claims of the '775 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Ninth Defense

The manufacture, use, sale, offer for sale, or importation of the drug product described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not – if marketed – infringe any valid and/or enforceable claim of U.S. Patent No. 7,211,267 ("the '267 patent"), either literally or under the doctrine of equivalents.

Tenth Defense

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '267 patent.

Eleventh Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '267 patent.

Twelfth Defense

The claims of the '267 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Thirteenth Defense

The manufacture, use, sale, offer for sale, or importation of the drug product described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not – if marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of U.S. Patent No. 7,232,572 (“the ‘572 patent”), either literally or under the doctrine of equivalents.

Fourteenth Defense

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ‘572 patent.

Fifteenth Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ‘572 patent.

Sixteenth Defense

The claims of the ‘572 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Seventeenth Defense

The Court lacks subject matter jurisdiction over any claims asserted against LPI.

Eighteenth Defense

LPI is not a proper party to this action.

Nineteenth Defense

The Complaint fails to state a claim upon which relief may be granted.

Twentieth Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIM

Lupin Ltd. (“Lupin”) asserts the following Counterclaim against Plaintiffs/Counterclaim-Defendants The Research Foundation of State University of New York, New York University, Galderma Laboratories Inc., and Galderma Laboratories, L.P. (“Plaintiffs/Counterclaim Defendants”):¹

PARTIES

1. Lupin Ltd. is a company organized and existing under the laws of India, having a place of business at Laxmi Towers “B” Wing, 5th floor, Banda Kurla Complex, Mumbai 400 051, India.

2. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

3. Upon information and belief, Plaintiff/Counterclaim Defendant The Research Foundation of State University of New York purports to be a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business at 35 State Street, Albany, New York 12207.

4. Upon information and belief, Plaintiff/Counterclaim Defendant New York University purports to be a private, non-profit corporation organized and existing under the laws of the State of New York, having a principal place of business at 70 Washington Square South, New York, New York 10012.

5. Upon information and belief, Plaintiff/Counterclaim Defendant Galderma Laboratories Inc. purports to be a corporation organized and existing under the laws of the State

¹ Lupin Pharmaceuticals, Inc. (“LPI”) asserts that it is not a proper party to this action. However, in the event the Court determines that LPI is properly named as a defendant to Plaintiffs’ Complaint, LPI adopts and joins Lupin Ltd.’s Counterclaim against Plaintiffs.

of Delaware, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

6. Upon information and belief, Plaintiff/Counterclaim Defendant Galderma Laboratories, L.P. purports to be a privately held partnership registered in the state of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

NATURE OF THE ACTION

7. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

JURISDICTION AND VENUE

8. This Court has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Lupin in this District, and/or because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

PATENTS-IN-SUIT

11. On or about August 4, 1998, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,789,395 ("the '395 patent"), entitled "Method of Using Tetracycline Compounds for Inhibition of Endogenous Nitric Oxide Production," to Ashok R. Amin, Steven B. Abramson, Lorne M. Golub, Nungavaram S. Ramamurthy, Thomas F. McNamara, Robert A. Greenwald, and Howard Trachtman.

12. On or about July 6, 1999, the PTO issued U.S. Patent No. 5,919,775 (“the ‘775 patent”), entitled “Method for Inhibiting Expression of Inducible Nitric Oxide Synthase with Tetracycline,” to Ashok R. Amin, Steven B. Abramson, Lorne M. Golub, Nungavaram S. Ramamurthy, Thomas F. McNamara, Robert A. Greenwald, and Howard Trachtman.

13. On or about May 1, 2007, the PTO issued U.S. Patent No. 7,211,267 (“the ‘267 patent”), entitled “Methods of Treating Acne,” to Robert A. Ashley.

14. On or about June 19, 2007, the PTO issued U.S. Patent No. 7,232,572 (“the ‘572 patent”), entitled “Methods of Treating Rosacea,” to Robert A. Ashley.

15. Plaintiffs/Counterclaim-Defendants purport and claim to own, and/or have the right to enforce, the ‘395, ‘775, ‘267, and ‘572 patents.

16. On July 2, 2009, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘395, ‘775, ‘267, and ‘572 patents under 35 U.S.C. §§ 271(a), (b), (c) and (e)(2)(A).

COUNT I
(Declaratory Judgment of Non-Infringement of the ‘395 Patent)

17. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

18. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the ‘395 patent.

19. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘395 patent, either directly or indirectly.

20. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '395 patent, either directly or indirectly.

COUNT II
(Declaratory Judgment of Invalidity of the '395 Patent)

21. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

22. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '395 patent.

23. The claims of the '395 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

24. Lupin is entitled to a judicial declaration that the claims of the '395 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '775 Patent)

25. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

26. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '775 patent.

27. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if

marketed, infringe any valid and/or enforceable claim of the '775 patent, either directly or indirectly.

28. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '775 patent, either directly or indirectly.

COUNT IV
(Declaratory Judgment of Invalidity of the '775 Patent)

29. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

30. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '775 patent.

31. The claims of the '775 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

32. Lupin is entitled to a judicial declaration that the claims of the '775 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '267 Patent)

33. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

34. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '267 patent.

35. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '267 patent, either directly or indirectly.

36. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '267 patent, either directly or indirectly.

COUNT VI
(Declaratory Judgment of Invalidity of the '267 Patent)

37. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

38. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '267 patent.

39. The claims of the '267 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

40. Lupin is entitled to a judicial declaration that the claims of the '267 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '572 Patent)

41. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

42. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '572 patent.

43. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '572 patent, either directly or indirectly.

44. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '572 patent, either directly or indirectly.

COUNT VIII
(Declaratory Judgment of Invalidity of the '572 Patent)

45. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

46. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '572 patent.

47. The claims of the '572 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

48. Lupin is entitled to a judicial declaration that the claims of the '572 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

- (a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '395 patent, either directly or indirectly;
- (b) Declaring that the claims of the '395 patent are invalid;
- (c) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '775 patent, either directly or indirectly;
- (d) Declaring that the claims of the '775 patent are invalid;
- (e) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '267 patent, either directly or indirectly;
- (f) Declaring that the claims of the '267 patent are invalid;
- (g) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '572 patent, either directly or indirectly;
- (h) Declaring that the claims of the '572 patent are invalid;
- (i) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Lupin;
- (j) Awarding Lupin its costs;
- (k) Declaring this case exceptional and awarding Lupin its reasonable attorneys' fees and costs under 35 U.S.C. § 285; and
- (l) Awarding Lupin such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lupin Ltd. and LPI hereby demand a trial by jury as to all issues so triable.

Dated: August 31, 2009.

Respectfully submitted,

PHILLIPS, GOLDMAN & SPENCE, P.A.

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